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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,918	12/16/2005	Matthew Baker	MER-142	1856
2387 7590 09/14/2007 OLSON & HIERL, LTD. 20 NORTH WACKER DRIVE 36TH FLOOR CHICAGO, IL 60606			EXAMINER CARLSON, KAREN C	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 09/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,918	Applicant(s) BAKER ET AL.	
	Examiner Karen Cochran Carlson, Ph.D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

This Office Action is in response to the paper filed July 23, 2007.

Claims 1-8 and 10-16 have been cancelled. Claims 9 and 17 are currently under examination.

Benefit of priority is to June 26, 2003.

Withdrawal of Objections and Rejections:

The objection to the disclosure because the sequence identification numbers do not accompany the sequences in accordance to 37 CFR 1.821+, because the sequence at page 4, line 1 and in Claim 9 is not found in the sequence listing. SEQ ID NO: 1 appears to be the sequence intended; however, SEQ ID NO: 1 has an Ala preceeding the N-terminal Cys, and because the abstract was not present in the disclosure with withdrawn.

The rejection of Claim 9 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn.

The rejection of Claim 9 under 35 U.S.C. 112, second paragraph, is withdrawn.

The rejection of Claim 9 under 35 U.S.C. 102(b) as being anticipated by Scharf et al., (1989; Primary structures of new 'iso-hirudins'. FEBS Letters 255 (1): 105-110), is withdrawn.

The rejection of Claim 9 under 35 U.S.C. 103(a) as being unpatentable over Scharf et al., (1989; Primary structures of new 'iso-hirudins'. FEBS Letters 255 (1): 105-110), is withdrawn.

Maintenance of objections:

The disclosure is again objected to because of the following informalities:

The priority at page 1 should include the foreign priority information.

Appropriate correction is required.

Art Unit: 1656

Applicants argue that they are not aware that there is a requirement to include foreign priority information in the specification. The point of claiming priority in the specification is to declare your intended benefit of priority. The bibliographical data sheet, which includes the foreign priority data, must match the priority set forth in the specification or a printer rush will occur upon allowance of the claims. Thus, for all practical purposes, now is the time to clarify what Applicants intend their priority to be.

New Rejections:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Krstenansky et al. (January 29, 1992; EP 0 468 448 A2).

Krstenansky et al. teach 11 amino acid sequence within instant SEQ ID NO: 1 as their own SEQ ID NO: 1 (A1), which is TPKPESHNDGD (page 6, top; **Claim 9**). At page 2, para. 5, Applicants note that they had previously discovered that this region of hirudin is responsible at least in part for its anticoagulant activity, which is why they are using it as A1 of the formula 1. Therefore, to assess this activity it is reasonable to conclude that Krstenansky et al. placed this fragment of hirudin into a pharmaceutical composition (**Claim 17**).

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Maraganore et al. (USP 5,256,559 issued October 28, 1993).

Art Unit: 1656

Maraganore et al. teach a 16 amino acid sequence within instant SEQ ID NO: 1 as VTGEGTPKPESHNDGD (Col. 6, line 38-39; **Claim 9**).

With regard to the now withdrawn rejections, Applicants urged that the portion of SEQ ID NO: 1 was directed to immunogenic portions of hirudin. This is not in the claims. The claims state that the portion will bind MHC class II proteins. Regardless, if the portion is found, then the structure naturally provides for the function.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER